



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3885]

Agency Information Collection Activities; Proposed Collection; Comment Request; Center for Tobacco Products, Food and Drug Administration Funded Trainee/Scholar Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on "Center for Tobacco Products, Food and Drug Administration Funded Trainee/Scholar Survey."

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-3885 for "Center for Tobacco Products, Food and Drug Administration Funded Trainee/Scholar Survey." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

(2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Center for Tobacco Products, Food and Drug Administration Funded Trainee/Scholar Survey

OMB Control Number 0910-NEW

The Tobacco Control Act (Pub. L. 111-31) amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA's Center for Tobacco Products (CTP) and the National Institutes of Health maintain an interagency partnership to foster the development of the emerging field of tobacco regulatory science (TRS). This study will use the CTP, FDA Funded Trainee/Scholar Survey to gather data on the characteristics, activities, and impact of training programs funded by the CTP and other partners. This evaluation will also determine how CTP-funded research and associated training programs and activities increase knowledge and skills related to TRS and interest to pursue careers in a TRS-related field. This survey provides support to determine the extent to which programs and activities generate positive impacts to increase the number of researchers who focus on TRS and TRS-related topics, specifically within CTP's priority domains. The survey builds upon previous evaluations of trainees and training activities and provides necessary evidence to inform FDA decision making. The web survey will gather responses from Tobacco Centers of Regulatory Science (TCORS) trainees and other CTP-funded trainees and scholars. Results will provide insights and directions to support future training and funding investments.

FDA CTP will use findings from this study to determine whether its TRS training support investments lead to meaningful change that supports CTP aims, and to inform decisions about potential future investments. CTP's training support intends to build additional capacity for TRS that establishes an evidence base related to CTP's research priorities so that FDA regulations, communications, and application review are founded on rigorous, relevant scientific study.

Respondents include current and former TCORS or other CTP-funded trainees and trainee principal investigators (PIs) or training directors. PIs and training directors will be asked to provide trainee names and email addresses and encourage trainees to participate in the survey. Current and former trainees will be asked to read an informed consent and take a brief web-based survey.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Type of Respondent/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Current or Former Trainee/Scholar					
Lead Letter	350	1	350	.025 (2 minutes)	9
Email invitation	350	1	350	.016 (1 minute)	6
Informed consent	298	1	298	.033 (2 minutes)	10
Survey	298	1	298	.16 (10 minutes)	48
Followup email	176	3	528	.016 (1 minute)	8
PI or Training Director					
Trainee list email	350	1	350	.16 (10 minutes)	56
Notification email	350	1	350	.016 (1 minute)	6
Total					143

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 1 summarizes the total annual burden hours estimated for this information collection. There is no cost to participants other than their time. The total estimated annualized burden hours are 143. A total of approximately 350 trainees will be invited to participate in the

web survey. Burden hours were estimated based on experience with prior similar survey activities and information obtained from informal testing by contractor staff.

Dated: September 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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